UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/530,274 | 12/06/2005 | Wen-Hwa Lee | 21105.0004U2 | 3628 |

23859 7590 03/31/2008

NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

| EXAMINER | |
|---|---|
| BLANCHARD, DAVID J | |
| ART UNIT | PAPER NUMBER |
| 1643 | |
| MAIL DATE | DELIVERY MODE |
| 03/31/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/530,274 | LEE ET AL. | |
| | Examiner | Art Unit | |
| | David J. Blanchard | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 April 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5 and 8-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5 and 8-38* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature of claim 36 is a molecule or ligand that lessens proliferation when contacted with proliferating cells. In view of this Chen et al (Molecular and Cellular Biology, 17(10):6049-6056, October 1997, IDS reference A6 filed 4/5/05) reads on the claim. Chen et al teach anti-HEC monoclonal antibody 9G3 (MAb 9G3) which when microinjected into carcinoma cells renders the cells nonviable with multiple, fragmented micronuclei. Thus, Chen et al teach a molecule (e.g., MAb 9G3) that lessens proliferation when contacted with proliferating cells (e.g., carcinoma cells). Applicant is reminded that the method in which the molecule or ligand were produced is immaterial to their patentability. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 37-38, drawn to the molecule or ligand IBT4282, which lessens the proliferation when contacted with proliferating cells and a composition comprising such.

Group II, claims 37-38, drawn to the molecule or ligand IBT6432, which lessens the proliferation when contacted with proliferating cells and a composition comprising such.

Group III, claims 37-38, drawn to the molecule or ligand IBT11830, which lessens the proliferation when contacted with proliferating cells and a composition comprising such.

Group IV, claims 37-38, drawn to the molecule or ligand IBT12008, which lessens the proliferation when contacted with proliferating cells and a composition comprising such.

Group V, claims 37-38, drawn to the molecule or ligand IBT13131, which lessens the proliferation when contacted with proliferating cells and a composition comprising such.

Group VI, claims 37-38, drawn to the molecule or ligand IBT14664, which lessens the proliferation when contacted with proliferating cells and a composition comprising such.

Group VII, claims 37-38, drawn to the molecule or ligand IBT15154, which lessens the proliferation when contacted with proliferating cells and a composition comprising such.

Group VIII, claims 2-5 and 8-16, drawn to a method of treating or preventing a cancer comprising inhibiting the interaction between Hec1 and Nek2 using a small molecule drug, thereby lessening cell proliferation.

Group IX, claims 2-5 and 8-16, drawn to a method of treating or preventing a cancer comprising inhibiting the interaction between Hec1 and Nek2 using an antibody, thereby lessening cell proliferation.

Group X, claims 2-5 and 8-16, drawn to a method of treating or preventing a cancer comprising inhibiting the interaction between Hec1 and Nek2 by reducing the level of Hec1 and Nek2, thereby lessening cell proliferation.

Group XI, claims 2-5 and 8-16, drawn to a method of treating or preventing a cancer comprising inhibiting the interaction between Hec1 and Hint1 using a small molecule drug, thereby lessening cell proliferation.

Group XII, claims 2-5 and 8-16, drawn to a method of treating or preventing a cancer comprising inhibiting the interaction between Hec1 and Hint1 using an antibody, thereby lessening cell proliferation.

Group XIII, claims 2-5 and 8-16, drawn to a method of treating or preventing a cancer comprising inhibiting the interaction between Hec1 and Hint1 by reducing the level of Hec1 and Hint1, thereby lessening cell proliferation.

Group XIV, claims 2-5, 8-10 and 17-20, drawn to a method of treating or preventing a stenosis comprising inhibiting the interaction between Hec1 and Nek2 using a small molecule drug, thereby lessening cell proliferation.

Group XV, claims 2-5, 8-10 and 17-20, drawn to a method of treating or preventing a stenosis comprising inhibiting the interaction between Hec1 and Nek2 using an antibody, thereby lessening cell proliferation.

Group XVI, claims 2-5, 8-10 and 17-20, drawn to a method of treating or preventing a stenosis comprising inhibiting the interaction between Hec1 and Nek2 by reducing the level of Hec1 and Nek2, thereby lessening cell proliferation.

Group XVII, claims 2-5, 8-10 and 17-20, drawn to a method of treating or preventing a stenosis comprising inhibiting the interaction between Hec1 and Hint1 using a small molecule drug, thereby lessening cell proliferation.

Group XVIII, claims 2-5, 8-10 and 17-20, drawn to a method of treating or preventing a stenosis comprising inhibiting the interaction between Hec1 and Hint1 using an antibody, thereby lessening cell proliferation.

Group XIX, claims 2-5, 8-10 and 17-20, drawn to a method of treating or preventing a stenosis comprising inhibiting the interaction between Hec1 and Hint1 by reducing the level of Hec1 and Hint1, thereby lessening cell proliferation.

Group XX, claims 22 and 24-27, drawn to a method of identifying a compound that reduces interaction between Hec1 and Nek2 comprising (a) contacting Hec1 and Nek2 in the relative absence of the compound, (b) contacting Hec1 and Nek2 in the relative presence of the compound, determining the relative amount of interaction between Hec1 and Nek2 in (a) and (b) by immunoprecipitation and comparing the relative amount of interaction wherein is the presence of the compound causes less interaction than the relative absence of the compound, the compound is identified as a compound that reduces an interaction between Hec1 and Nek2.

Group XXI, claims 23-27, drawn to a method of identifying a compound that reduces interaction between Hec1 and Hint1 comprising (a) contacting Hec1 and Hint1 in the relative absence of the compound, (b) contacting Hec1 and Hint1 in the relative presence of the compound, determining the relative amount of interaction between Hec1 and Hint1 in (a) and (b) by immunoprecipitation and comparing the relative amount of interaction wherein is the presence of the compound causes less interaction than the relative absence of the compound, the compound is identified as a compound that reduces an interaction between Hec1 and Hint1.

Group XXII, claims 28-31, drawn to a method of identifying a molecule that interferes with a function of Hec1 and inhibits cell proliferation comprising contacting a sample comprising cells with the molecule wherein a decrease in function relative to a sample

comprising proliferating cells not contacted with the molecule identifies the molecule that inhibit proliferation of the cells.

Group XXIII, claims 28-31, drawn to a method of identifying a molecule that interferes with a function of Nek2 and inhibits cell proliferation comprising contacting a sample comprising cells with the molecule wherein a decrease in function relative to a sample comprising proliferating cells not contacted with the molecule identifies the molecule that inhibit proliferation of the cells.

Group XXIV, claims 28-31, drawn to a method of identifying a molecule that interferes with a function of Hint1 and inhibits cell proliferation comprising contacting a sample comprising cells with the molecule wherein a decrease in function relative to a sample comprising proliferating cells not contacted with the molecule identifies the molecule that inhibit proliferation of the cells.

Group XXV, claims 28-31, drawn to a method of identifying a molecule that interferes with a function of Hec1, Nek2 and Hint1 and inhibits cell proliferation comprising contacting a sample comprising cells with the molecule wherein a decrease in function relative to a sample comprising proliferating cells not contacted with the molecule identifies the molecule that inhibit proliferation of the cells.

Group XXVI, claims 32-35, drawn to a method of identifying a potential ligand of a Hec1 protein comprising synthesizing the potential ligand, contacting the potential ligand with a Hec1 protein domain-containing protein and determining whether the potential ligand binds to the Hec1 protein domain-containing protein.

2. This application contains claims directed to the following patentably distinct species of carcinoma and sarcoma. If applicant elects one of inventions VIII-XIII, applicant is required to further elect a single carcinoma species of claim 13, or a single sarcoma species of claim 15, or retinoblastoma, or glioblastoma, or neuroblastoma.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

3. This application contains claims directed to the following patentably distinct species of carcinoma and sarcoma. If applicant elects one of inventions XIV-XIX, applicant is required to further elect a single stenosis species of claim 18. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the

election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

4. Claim 36 links inventions I-VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 36.

5. Claim 1 links inventions VIII-XIX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 1.

6. Claim 21 links inventions XX-XXI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 21.

Upon the indication of allowability of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. The inventions listed as Groups I-XXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Chen et al the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 36 is not special.

Inventions of Groups I-VII represent separate and distinct products, which are structurally and chemically different from each other. The molecules IBT4282, IBT6432, IBT11830, IBT12008, IBT13131, IBT14664 and IBT15154 have different structures and are not required one for the other. Further, art on one structure would likely not be art on the others. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-VII are patentably distinct.

The methods of Inventions VIII-XXVI differ in the method objectives, method steps and parameters and in the reagents used. Inventions VIII-X recite methods of treating or preventing a cancer comprising inhibiting the interaction between Hec1 and Nek2 using a small molecule drug, an antibody and reducing the level of Hec1 and Nek2, respectively; Inventions XI-XIII recite methods of treating or preventing a cancer comprising inhibiting the interaction between Hec1 and Hint1 using a small molecule drug, an antibody and reducing the level of Hec1 and Nek2, respectively; Inventions

XIV-XVI recite methods of treating stenosis comprising inhibiting the interaction between Hec1 and Nek2 using a small molecule drug, an antibody and reducing the level of Hec1 and Nek2, respectively; Inventions XVII-XIX recite methods of treating stenosis comprising inhibiting the interaction between Hec1 and Hint1 using a small molecule drug, an antibody and reducing the level of Hec1 and Nek2, respectively; Invention XX recite a method of identifying a compound that reduces interaction between Hec1 and Nek2 comprising (a) contacting Hec1 and Nek2 in the relative absence of the compound, (b) contacting Hec1 and Nek2 in the relative presence of the compound, determining the relative amount of interaction between Hec1 and Nek2 in (a) and (b) by immunoprecipitation and comparing the relative amount of interaction wherein is the presence of the compound causes less interaction than the relative absence of the compound, the compound is identified as a compound that reduces an interaction between Hec1 and Nek2; Invention XXI recite a method of identifying a compound that reduces interaction between Hec1 and Hint1 comprising (a) contacting Hec1 and Hint1 in the relative absence of the compound, (b) contacting Hec1 and Hint1 in the relative presence of the compound, determining the relative amount of interaction between Hec1 and Hint1 in (a) and (b) by immunoprecipitation and comparing the relative amount of interaction wherein is the presence of the compound causes less interaction than the relative absence of the compound, the compound is identified as a compound that reduces an interaction between Hec1 and Hint1; Inventions XXII-XXV recite methods of identifying a molecule that interferes with a function of Hec1, Nek2, Hint1, or Hec1, Nek2 and Hint1, and inhibits cell proliferation comprising contacting a sample comprising cells with the molecule wherein a decrease in function relative to a sample comprising proliferating cells not contacted with the molecule identifies the molecule that inhibit proliferation of the cells, respectively; Invention XXVI recites a method of identifying a potential ligand of a Hec1 protein comprising synthesizing the potential ligand, contacting the potential ligand with a Hec1 protein domain-containing protein and determining whether the potential ligand binds to the Hec1 protein domain-containing protein. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of

different patentability issues. Thus Inventions VIII-XXVI are separate and distinct in having different method objectives, method steps and parameters and in the reagents used and different endpoints and are patentably distinct.

Inventions I-VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the molecules of Groups I-VII can be used in a materially different method such as the therapeutic methods of Groups XI, XIV and XVII in addition to the materially different therapeutic method of Group VIII.

8. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To

reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643